UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAR 26 2009

Jeffrey P. Kushan
Sidley Austin, LLP
1501 K Street, N.W.
Washington, DC 20005

In Re: Patent Term Extension
Application for
U.S. Patent No. 7,060,269

# NOTICE OF FINAL DETERMINATION AND REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 7,060,269, claims of which cover a method of using LUCENTIS® (ranibizumab), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 17 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Applicant also has applied for patent term extension of U.S. Patent No. 6,407,213 and U.S. Patent No. 6,884,879 based on the regulatory review period for the human biologic drug product LUCENTIS® (ranibizumab).

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance, unless applicant elects a different patent. In the absence of an election by applicant within ONE MONTH of the date of this notice, and in accordance with 37 CFR 1.785(b), the applications for patent term extension of U.S. Patent No. 6,884,879 and U.S. Patent No. 7,060,269 will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted, i.e., a certificate of extension will be issued to U.S. Patent No 6,407,213 for a period of 378 days.

In the absence of a request for reconsideration, and if U.S. Patent No. 7,060,269 is elected, the Director will issue to the applicant a certificate of extension, under seal, for a period of 17 days in U.S. Patent No. 7,060,269.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of May 29, 2008 (73 Fed. Reg. 30949). Under 35 U.S.C. § 156(c):

| | | |
|---|---|---|
| Period of Extension | = | ½ (Testing Phase) + Approval Phase |
| | = | ½ (2,247 days - 2,247 days) + (183 days - 166 days) |
| | = | 17 days |

Since the regulatory review period began November 6, 1999, before the patent issued June 13, 2006), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From November 6, 1999, to and including, June 13, 2006, is 2,403 days (2,247 days in the testing phase and 166 days in the approval phase); this period is subtracted for the number of days occurring in the testing phase and approval phase according to the FDA's determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

| | |
|---|---|
| U.S. Patent No.: | 7,060,269 |
| Granted: | June 13, 2006 |
| Original Expiration Date[1]: | July 4, 2019 |
| Applicant: | Manuel Baca et al. |
| Owner of Record: | Genentech, Inc. |
| Title: | Anti-VEGF Antibodies |
| Product Trade Name: | LUCENTIS® (ranibizumab) |
| Term Extended: | 17 days |
| Expiration Date of Extension: | July 21, 2019 |

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450

By FAX: (571) 273-7755

[1]Subject to the provisions of 35 U.S.C. § 41(b).

Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: LUCENTIS® (ranibizumab)
Docket No.: FDA-2007-E-0459